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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/821,719	03/29/2001	Kathleen A. Donovan	07039-260001	4609

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EXAMINER

JAMROZ, MARGARET E

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 03/07/2002

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/821,719

Applicant(s)

DONOVAN ET AL.

Examiner

Margaret E Jamroz

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-27 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *restriction election facsimile*.

Art Unit: 1644

DETAILED ACTION

1. The location of your application in the PTO has changed. To aid in correlating papers for this application, all further correspondence regarding this application should be directed to Megan Jamroz in Art Unit 1644, Technology Center 1600.

Restriction Requirement

2. Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Ph.D., Supervisory Patent Examiner at Paula.Hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

3. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-10 and 15, drawn to a method of quantitation of IL-1 beta in a bone marrow preparation comprising comparing IL-6 levels with IL-1beta levels; classified in Class 435, subclass 7.1.

II. Claims 11-14, drawn to a method of identifying a patient with multiple myeloma-related plasmaproliferative disorder comprising comparing IL-2 levels; classified in Class 435, subclass 7.92.

III. Claim 16, drawn to a method of treating a patient comprising administering an inhibitor of interleukin-1J; classified in Class 424, subclass 198.1.

IV. Claims 17-22, drawn to a method of inhibiting IL-6 production in a patient comprising administering an inhibitor of IL-1beta, wherein the inhibitor is an anti-IL-1 β antibody; classified in Class 424, subclass 130.1.

V. Claims 17-22, drawn to a method of inhibiting IL-6 production in a patient comprising administering an inhibitor of IL-1beta, wherein the inhibitor is a soluble IL-1 receptor type I; classified in Class 424, subclass 184.1.

VI. Claims 17-22, drawn to a method of inhibiting IL-6 production in a patient comprising administering an inhibitor of IL-1beta, wherein the inhibitor is a soluble IL-1 receptor type II; classified in Class 424, subclass 184.1.

VII. Claims 17-22, drawn to a method of inhibiting IL-6 production in a patient comprising administering an inhibitor of IL-1beta, wherein the inhibitor is an IL-1 receptor antagonist; classified in Class 424, subclass 184.1.

VIII. Claims 17-22, drawn to a method of inhibiting IL-6 production in a patient comprising administering an inhibitor of IL-1beta, wherein the inhibitor is an IL-1 TRAP; classified in Class 424, subclass 184.1.

IX. Claims 23-27, drawn to a kit comprising an inhibitor of bioactive IL-1beta, a negative control for the inhibitor, and a positive control for bioactive IL-1beta, wherein the inhibitor is an anti-IL-1 β antibody; classified in Class 435, subclass 810.

X. Claims 23-27, drawn to a kit comprising an inhibitor of bioactive IL-1beta, a negative control for the inhibitor, and a positive control for bioactive IL-1beta, wherein the inhibitor is a soluble IL-1 receptor type I; classified in Class 435, subclass 810.

XI. Claims 23-27, drawn to a kit comprising an inhibitor of bioactive IL-1beta, a negative control for the inhibitor, and a positive control for bioactive IL-1beta, wherein the inhibitor is a soluble IL-1 receptor type II; classified in Class 435, subclass 810.

XII. Claims 23-27, drawn to a kit comprising an inhibitor of bioactive IL-1beta, a negative control for the inhibitor, and a positive control for bioactive IL-1beta, wherein the inhibitor is an IL-1 receptor antagonist; classified in Class 435, subclass 810.

XIII. Claims 23-27, drawn to a kit comprising an inhibitor of bioactive IL-1beta, a negative control for the inhibitor, and a positive control for bioactive IL-1beta, wherein the inhibitor is an IL-1 TRAP; classified in Class 435, subclass 810.

4. Groups IX-XIII are different products. Anti-IL-1 β antibodies, a soluble IL-1 receptor type I, a soluble IL-1 receptor type II, an IL-1 receptor antagonist, and an IL-1 TRAP differ with respect to their structures and physicochemical properties; therefore each product is patentably distinct.

5. Groups I-VIII are different methods. The inventions as grouped in Groups I-VIII are distinct, each from the other, because they represent different inventive endeavors as one does not suggest the other; therefore, each method is patentably distinct.

Art Unit: 1644

6. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Moreover, a prior art search also requires a literature search, which would not be completely co-extensive. It is an undue burden for the examiner to search more than one invention. Therefore restriction for examination purposes as indicated is proper.


7. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Megan Jamroz whose telephone number is (703) 308-8365. The examiner can normally be reached Monday through Friday from 8:00 AM to 4:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Margaret (Megan) Jamroz, Ph.D.
Patent Examiner
Technology Center 1600
March 1, 2002


CHRISTINA Y. CHAN
SUPERVISORY PATENT EXAMINER
GROUP 1800-1600